REMARKS

Status of the patent application

Claims 1, 5-18 and 21-24 are pending and stand rejected in the present application, with claims 11-18 and 21-23 being withdrawn from consideration as directed to non-elected inventions, and claims 1, 5-10 and 24 under examination and stand rejected. With entry of the instant Response, claims 5-10 and 24 have been canceled, claim 1 has been amended, and new claims 25-29 have been added. Claim 1 has been amended to specify that the claimed fatty-acid amide hydrolase (FAAH) is encoded by SEQ ID No 42 (i.e., the full length human FAAH disclosed in the specification). Similarly, new claims 25 and 26 are respectively directed to the FAAHs encoded by the full length mouse and rat polynucleotide sequences disclosed in the specification (i.e., SEQ ID Nos 39 and 35). In addition, Applicants present herein new claims 27-29 which are directed to these polynucleotide sequences. Support for the claim amendment and new claims is replete in the specification, e.g., the original claims. No new matter has been introduced.

It is further noted that the amendments introduced herein have been made to improve clarity or to expedite prosecution of the subject application, and should not be construed as acquiescence of any ground of rejections.

The following remarked are provided to further address the issues raised in the Office Action.

Rejections Under The Second Paragraph of 35 U.S.C. §112

Claims 1, 5-10 and 24 were rejected as allegedly being indefinite. In view of the cancellation of claims 5-10 and 24 and the amendment to claim 1, the alleged indefiniteness issues are moot or no longer applicable. Applicants accordingly request that the rejections be withdrawn.

Rejections Under 35 U.S.C. §102(b)/103(a)

A number of references were cited in the Office Action to support rejection of the pending claims as allegedly being anticipated or obvious. These references were all cited in the information disclosure statements submitted by Applicants in the subject patent application, i.e., Maurelli et al. (1995), Deutsch et al. (1993), Cravatt et al. (1995), Ohkawa et al. (1990), Ueda et al. (1995), Koutek et al. (1994), Scopes (1987), and Mayaux et al. (1990). The Examiner asserts that some of these references individually teach enzymes which appear to be the fatty-acid amide hydrolases disclosed in the present invention. The Examiner further alleges that the combined teachings of some of these references render the previously presented claims obvious.

In response, Applicants note that other than claim 1, the pending claims which have been under examination are all cancelled. Claim 1 has also been amended to specify a FAAH encoded by a specific polynucleotide sequence. Therefore, the instant rejections should no longer apply. Nevertheless, Applicants provide the remarks below to address any rejection based on these references that might be rendered against the currently presented claims.

The presently claimed invention relates to isolated fatty-acid amide hydrolase (FAAH) polypeptides or polynucleotides which are encoded by specific polynucleotide sequences (i.e., SEQ ID Nos 35, 39 and 42). Applicants acknowledge that some of the cited references may have described certain enzymatic activities which are related to hydrolysis of fatty-acid amides. However, there is no disclosure of <u>isolated or purified</u> fatty-acid amide hydrolases as that disclosed in the subject specification. Instead, the references cited in the Office Action may have at most discussed some related enzymes present in some unpurified and un-isolated crude preparations. For this reason alone, none of the cited references could anticipate the presently claimed invention. The claimed invention is additionally novel over the cited art also because the cited references clearly do not disclose any of the specific polynucleotide sequences recited in the present claims.

In addition, the presently claimed invention is certainly non-obvious over

disclosures of the cited art. To render the claimed invention prima facie obvious, three basic elements must be met: (I) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §§ 706.02(j) and 2143. However, none of these elements can be satisfied in the present case. First, the combined teachings of the cited art certainly do not teach each and every element of the claimed invention. Nowhere in the cited art is disclosed any of the specific polynucleotide sequences recited in the present claims. In addition, the cited art does not provide the required motivation for one to combine teachings of prior art and a reasonable expectation of success in order to achieve a FAAH as presently claimed. Therefore, the claimed invention is undoubtedly non-obvious over the teachings of the cited art.

It is further noted that the claimed FAAH sequences can not be rendered obvious on the ground that the enzymes discussed in the cited art may inherently harbor such structural characteristics, as alleged in the Office Action. The courts have long held that a particular DNA sequence is not rendered obvious by prior art disclosure of a protein encoded by the sequence together with knowledge of the genetic code and methods for generating DNA that encodes proteins. This is so even if the prior art also teaches the polynucleotide sequence encoding that same protein from a different organism. See, e.g. *In re Deuel*, 34 USPQ2d 1210 (Fed. Cir. 1995); and *In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993). Also, it is well established in the law that "[t]he fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness." *See, e.g., In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); and also MPEP § 2144.08.

In the instant case, there is no evidence (e.g., structural information) that the unpurified enzymes discussed in the art are indeed fatty-acid amide hydrolases. Thus,

the specific FAAH polypeptides recited in the present claims are certainly not obvious over references that teach nothing more than crude sub-cellular fractions that hydrolyze related substrates and generic teachings of how to purify and isolate proteins. In addition, even if the enzymes discussed in the cited art are fatty-acid amide hydrolases, there is no indication that any of those enzymes is the same FAAH species as one of the presently claimed FAAH enzymes. There is no specific amino acid sequence or other structural information described in the cited references with regard to the alleged FAAH enzymes. Applying the above noted case law, one would readily reach the conclusion that the specific FAAHs as presently claimed cannot be obvious over any generic disclosure of fatty-acid amide hydrolases. Therefore, it will be wholly improper to assert that the cited art could render the presently claimed specific FAAHs obvious.

For all the reasons stated above, Applicants respectfully request that the rejection of the claims under 35 U.S.C. §102(b)/103(a) be withdrawn.

Restriction requirement

Applicants have previously made elections of claims 1, 5-10 and 24 and Seq ID No. 42. Applicants acknowledge that restriction can be properly made among claimed inventions that are independent or distinct. However, it is also noted that if the search and examination of all the claims in an application can be made without serious burden, the examiner should examine them on the merits. See MPEP § 803. Further, Applicants note that restrictions among independent or distinct inventions are discretionary, not mandatory. For the reasons stated below, Applicants respectfully request the Examiner to rejoin SEQ ID Nos 35 and 39 (as reflected in new claims 25 and 26) with the elected SEQ ID No 42 for examination in the instant patent application. In addition, entry and consideration of new claims 27-29, which are directed to polynucleotides corresponding to the same sequences, are also respectfully urged.

By the present amendment, Applicants have limited the claims to the full length sequences of three specific FAAHs, and thereby greatly reduced issues and complexity

in their examination. Due to the claim cancellation and amendment introduce herein, Applicants believe substantial examination of all three sequences by the Examiner is significantly simplified. To this end, Applicants note that polypeptide sequences of the three FAAH species currently claimed have already been examined together by the Examiner and issued in the parent application Serial No. 08/743,168 (now U.S. patent No. 6,271,015). Therefore, there would be no additional burden on the Examiner to consider all three polynucleotide sequences together.

Further, examining the new claims introduced herein will allow Applicants to not unnecessarily file additional divisional or continuation application to pursue the restricted sequences. Therefore, this would also be conducive to reducing future backlog at the U.S. Patent and Trademark Office, consistent with the goal the patent office has been striving to achieve.

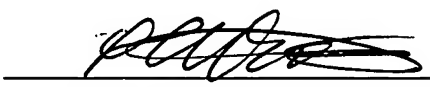
CONCLUSION

In view of the foregoing, Applicants believe all claims currently under examination are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-784-2937. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments regarding the subject application to our Deposit Account No. 19-0962.

Respectfully submitted,

May 24, 2007
Date



Hugh Wang, Reg. No. 47,163

THE SCRIPPS RESEARCH INSTITUTE
Office of Patent Counsel
10550 North Torrey Pines Road
Mail Drop TPC-8
La Jolla, California 92037
(858) 784-2937

P:\Hugh\485\2007.05.Resp.OA.wpd